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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/998,923 | 12/03/2001 | Laura P. Hale | 1579-628 | 4251 |

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| EXAMINER | |
|---|---|
| UNGAR, SUSAN NMN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1642 | |

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/998,923 | HALE ET AL. | |
| | Examiner | Art Unit | |
| | Susan Ungar | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *07 May 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-18* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 1-18 are pending in the application and are currently under prosecution.

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

**Group 1.** Claims 1-7 are drawn to a method of diagnosing cancer in a test mammal comprising assaying for an elevated level of ZAG, classified in Class 435, subclass 7.1.

3. Claim 8 links inventions 2-8. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 8. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the

continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**Group 2.** Claims 8-13 are drawn to a method of diagnosing inflammatory disease or disorder of breast comprising assaying for an elevated level of ZAG, classified in Class 435, subclass 7.1.

**Group 3.** Claims 8-13 are drawn to a method of diagnosing inflammatory disease or disorder of prostate comprising assaying for an elevated level of ZAG, classified in Class 435, subclass 7.1.

**Group 4.** Claims 8-13 are drawn to a method of diagnosing inflammatory disease or disorder of liver comprising assaying for an elevated level of ZAG, classified in Class 435, subclass 7.1.

**Group 5.** Claims 8-13 are drawn to a method of diagnosing inflammatory disease or disorder of salivary comprising assaying for an elevated level of ZAG, classified in Class 435, subclass 7.1.

**Group 6.** Claims 8-13 are drawn to a method of diagnosing inflammatory disease or disorder of bronchial comprising assaying for an elevated level of ZAG, classified in Class 435, subclass 7.1.

**Group 7.** Claims 8-13 are drawn to a method of diagnosing inflammatory disease or disorder of gastrointestinal comprising assaying for an elevated level of ZAG, classified in Class 435, subclass 7.1.

**Group 8.** Claims 8-13 are drawn to a method of diagnosing inflammatory disease or disorder of sweat gland comprising assaying for an elevated level of ZAG, classified in Class 435, subclass 7.1.

4. Claim 14 links inventions 9-16. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 14. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211

**Group 9.** Claims 14-16, 19 are drawn to a method of inhibiting thymic atrophy in a mammal comprising administering an agent, an anti-ZAG antibody, that reduces the bioavailability of ZAG, wherein the mammal is an adult bearing a tumor/undergoing chemotherapy, classified in Class 424, subclass 130.1.

**Group 10.** Claims 14, 17-19 are drawn to a method of inhibiting thymic atrophy in a mammal comprising administering an agent, an anti-Zag

antibody, that reduces the bioavailability of ZAG, wherein the mammal has an infection/HIV, classified in Class 424, subclass 130.1.

**Group 11.** Claims 14-16, 19 are drawn to a method of inhibiting thymic atrophy in a mammal comprising administering an agent, an inhibiting thymic atrophy in a mammal comprising administering an agent, an antiandrogen, that reduces the bioavailability of ZAG, wherein the mammal is an adult bearing a tumor/undergoing chemotherapy, classified in Class 514, subclass 2+.

**Group 12.** Claims 14, 17-19 are drawn to a method of inhibiting thymic atrophy in a mammal comprising administering an agent, an antiandrogen, that reduces the bioavailability of ZAG, wherein the mammal has an infection/HIV, classified in Class 514, subclass 2+.

**Group 13.** Claims 14-16, 19 are drawn to a method of inhibiting thymic atrophy in a mammal comprising administering an agent, an anti-ZAG antibody, that inhibits the binding of ZAG to its receptor, wherein the mammal is an adult bearing a tumor/undergoing chemotherapy, classified in Class 424, subclass 130.1.

**Group 14.** Claims 14, 17-19 are drawn to a method of inhibiting thymic atrophy in a mammal comprising administering an agent, an anti-Zag antibody, that inhibits the binding of ZAG to its receptor, wherein the mammal has an infection/HIV, classified in Class 424, subclass 130.1.

**Group 15.** Claims 14-16, 19 are drawn to a method of inhibiting thymic atrophy in a mammal comprising administering an agent, an inhibiting thymic

atrophy in a mammal comprising administering an agent, an antiandrogen, that inhibits the binding of ZAG to its receptor, wherein the mammal is an adult bearing a tumor/undergoing chemotherapy, classified in Class 514, subclass 2+.

**Group 16.** Claims 14, 17-19 are drawn to a method of inhibiting thymic atrophy in a mammal comprising administering an agent, an antiandrogen, that inhibits the binding of ZAG to its receptor, wherein the mammal has an infection/HIV, classified in Class 514, subclass 2+.

5. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-16 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Group 1 is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising biological samples wherein the samples have different biochemistry and are from different body locations, wherein the samples are (a) plasma, (b) urine, (c) cerebrospinal fluid, (d) seminal fluid, (e) sweat, (f) nipple aspirate, all of claim 3, (g)serum (claim 7).

8. Group 1 is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising assay methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the assay methods are (a) immunoassay, (b) chromatography, (c) electrophoresis, (d) solid phase affinity, (e) densitometry of a Western blot, all of claim 4, (f) antigen capture (claim 5), (g) competitive immunoassay (claim 5).

9. Group 2 is further subject to election of a single disclosed species.

Claim 8 is generic to a plurality of disclosed patentably distinct species comprising assay methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the assay methods are (a) immunoassay, (b) chromatography, (c) electrophoresis, (d) solid phase affinity, (e) densitometry of a Western blot, all of claim 11, (f) antigen capture (claim 12), (g) competitive immunoassay (claim 12).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of

at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
December 17, 2003